

**FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP**
STEPHEN S. RABINOWITZ
srabinowitz@friedfrank.com
RANDY C. EISENSMITH (*Pro Hac Vice*)
randy.eisensmith@friedfrank.com
ONE NEW YORK PLAZA
NEW YORK, NEW YORK 10004-1980
Telephone: 212.859.8000
Facsimile: 212.859.4000

DURIE TANGRI LLP
DARALYN J. DURIE (SBN 169825)
ddurie@durietangri.com
JOSHUA H. LERNER (SBN 220755)
jlerner@durietangri.com
GENEVIEVE P. ROSLOFF (SBN 258234)
grosloff@duritangri.com
217 Leisdesdorff Street
San Francisco, CA 94111
Telephone: 415-362-6666
Facsimile: 415-236-6300

Attorneys for Plaintiffs
GENENTECH, INC. and
ROCHE PALO ALTO LLC

DUANE MORRIS LLP
JESSICA E. LA LONDE (SBN 235744)
One Market Plaza, Suite 2200
San Francisco, CA 94105-1127
Telephone: +1 415 957 3000
Facsimile: +1 415 957 3001
E-mail: jelalonde@duanemorris.com

RICHARD T. RUZICH (*pro hac vice*)
ROBERT M. GOULD (*pro hac vice*)
190 South LaSalle Street, Suite 3700
Chicago, IL 60603-3433
Telephone: +1 312 499 6700
Facsimile: +1 312 499 6701
E-mail: rtruzich@duanemorris.com
rmgould@duanemorris.com

KERRY B. MCTIGUE (*pro hac vice*)
505 9th Street N.W., Suite 1000
Washington, D.C. 20004-2166
Telephone: +1 202 776 7800
Facsimile: +1 202 776 7801
E-mail: kbmctigue@duanemorris.com

VINCENT L. CAPUANO (*pro hac vice*)
LAURA A. VOGEL (*pro hac vice*)
470 Atlantic Ave., Suite 500
Boston, MA 02210
Telephone +1 857 488-4200
Facsimile +1 857 488-4201
E-mail vcapuano@duanemorris.com
lavogel@duanemorris.com

Attorneys for Defendant
SANDOZ INC

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO**

GENENTECH, INC. and
ROCHE PALO ALTO, LLC,

Plaintiffs and Counterclaim Defendants,

v.

SANDOZ, INC.

Defendant and Counterclaim Plaintiff.

Case No. 3:11-cv-01925-JSW
Related Case No. 3:11-cv-02410-JSW

**JOINT CLAIM CONSTRUCTION AND
PREHEARING STATEMENT
PURSUANT TO PATENT LOCAL RULE
4-3**

Date: April 10, 2012
Time: 1:30 p.m.
Ctmm: 11, 19th Floor
Judge: Honorable Jeffrey S. White

Pursuant to Patent L.R. 4-3, Plaintiffs Genentech, Inc. (“Genentech”) and Roche Palo Alto LLC (“Roche Palo Alto”) and Defendant Sandoz Inc. (“Sandoz”), parties to the above-entitled action, jointly submit the following Joint Claim Construction and Prehearing Statement.

A. The Construction of Terms on Which the Parties Agree

The parties agree on the construction of the following terms in the claims of U.S. Patent No. 6,083,953 (“the ‘953 patent”).

Claim term	Agreed Construction
2-(2-amino-1,6-dihydro-6-oxo-purin-9-yl)methoxy-3-hydroxy-1-propanyl-L-valinate hydrochloride (claim 1)	valganciclovir hydrochloride
antiviral pharmaceutical composition (claim 2)	a pharmaceutical composition that has antiviral activity
treating (claim 3)	any treatment of a disease in an animal, including preventing, inhibiting or relieving the disease
animal (claim 3)	human or non-human animal
administering (claim 3)	introducing [the compound] into an animal’s body
is administered (claims 4, 6)	[the compound] is introduced into an animal’s body

B. Proposed Constructions of the Disputed Term

The parties disagree on the construction of a single term in claim 1 of the ‘953 patent. Their proposed constructions, and the intrinsic and extrinsic evidence upon which they rely, are set forth in the chart below.

Claim language (disputed term in bold)	Plaintiffs’ Proposed Construction and Evidence in Support	Defendant’s Proposed Constructions and Evidence in Support
2-(2-amino-1,6-dihydro-6-oxo-purin-9-yl)methoxy-3-hydroxy-1-propanyl-L-valinate hydrochloride in crystalline form	in a physical form having molecules arranged in a regularly repeating three dimensional pattern	prepared in a stable, solid physical form having molecules arranged in a regularly repeating three dimensional pattern

Claim language (disputed term in bold)	Plaintiffs' Proposed Construction and Evidence in Support	Defendant's Proposed Constructions and Evidence in Support
	<p><u>Intrinsic evidence:</u></p> <p>'953 patent specification:</p> <p>col. 1, ll. 19-27</p> <p>col. 5, ll. 47-52</p> <p>col. 10, ll. 50-55</p> <p>col. 14, ll. 49-50</p> <p>col. 15, ll. 5-9</p> <p>col. 20, ll. 56-65</p> <p>col. 21, ll. 19-49</p> <p>col. 23, l. 18 to col. 25, l. 22</p> <p>col. 27, l. 35 to col. 29, l. 33</p> <p>col. 30, claims 1, 2</p> <p>Application No. 08/281,893 as originally filed, pp. 19-20, 28-29, 31- 33, 41.</p> <p>Application No.08/453,223, Amendment dated May 24, 1996, pp. 2, 6, 14-17.</p> <p>Application No. 08/812,991, Response dated June 7, 1999, p. 2</p> <p>Application 09/418,535, Amendment dated August 24, 2000, p. 3.</p> <p><u>Extrinsic evidence:</u></p> <p>Remington's Pharmaceutical Sciences 172 (Alfonso R. Gennaro ed., (8th ed. 1990)</p> <p>23 The New Encyclopaedia Britannica 612-643 (Encyclopaedia Britannica, Inc., 15th ed. 1994)</p>	<p><u>Intrinsic evidence:</u></p> <p>'953 patent specification:</p> <p>col. 3, ll. 32-34</p> <p>col. 5, ll. 53-63</p> <p>col. 15, ll. 7-9</p> <p>col. 21, ll. 19-43</p> <p>Example 3B (col. 23, l. 49- col. 24, l. 8)</p> <p>Example 4 (col. 24, ll. 10- 33)</p> <p>Application No. 08/453,223, Paper No. 8 Amendment Under 37 CFR 1.111, filed May 28, 1996: pages 6, 14-17, and 45-46.</p> <p>Application No. 08/453,223, Paper No. 17, Appeal Brief, filed September 9, 1997: pages 4-5.</p> <p>Application No. 08/453,223, Paper No. 19, Reply Brief, filed January 12, 1998: pages 1-6.</p> <p>Application No. 08/453,223, Paper No. 23, Response to Final Rejection, filed September 8, 1998: pages 2-4</p> <p>Application No. 08/453,223, Declaration of Charles Dvorak, dated April 8, 1999: entire document.</p> <p>Application No. 08/453,223, Declaration of Yeun-Kwei Han, dated April 8, 1999: entire document.</p> <p>Application No. 08/453,223, Declaration of Hans Maag, dated April 8, 1999: entire document.</p> <p>Application No. 08/453,223, Paper No. 28, Appeal Brief, filed April 12, 1999: pages 3-10.</p> <p>Application No. 08/812,991,</p>

Claim language (disputed term in bold)	Plaintiffs' Proposed Construction and Evidence in Support	Defendant's Proposed Constructions and Evidence in Support
	<p>Order Construing Terms of U.S. Patent No. 6,083,953 from <i>Roche Palo Alto LLC v. Endo Pharmaceuticals, Inc.</i>, C.A. No. 10-261 (GMS) (D. Del. August 11, 2011)</p> <p>Valcyte Label (August 2010 Revision).</p> <p>Vogel's Textbook of Practical Organic Chemistry (B.S. Furniss et al., eds., 5th ed. 1989), pp. 135-136.</p> <p>S. Lohani and D.J.W. Grant, Thermodynamics of Polymorphs. <i>In</i>: Polymorphism in the Pharmaceutical Industry (R. Hilfiker, ed. 2006), p. 21</p> <p>J.K. Guillory, Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids. <i>In</i>: Polymorphism in Pharmaceutical Solids (H.G. Brittain, ed. 1999), pp. 184-185, 208-219.</p> <p>International Patent Application Publication WO 2008/122105 A1, Abstract and p.2.</p> <p>International Patent Application Publication WO 2009/024997 A1, Abstract and pp. 7-8.</p>	<p>Response to Office Action, dated June 10, 1999: pages 2-10.</p> <p>Application 09/418,535, Amendment dated August 24, 2000, pages 3-5.</p>

C. Terms Whose Construction Will Be Most Significant to the Resolution of the Case

The parties believe that the sole disputed term is the most significant for resolution of this case. Claim 1 is the only independent claim in the '953 patent. As such, claim 1 affects the remaining claims of the patent.

1 **D. The Anticipated Length of Time Necessary for the Claim Construction Hearing**

2 The parties believe that the claim construction hearing in this case and the related case should
3 be completed within three hours, to be equally divided between Plaintiffs Genentech and Roche Palo
4 Alto (1.5 hours) and Defendants Sandoz and Apotex (1.5 hours).

5 **E. Whether Any Party Proposes To Call One or More Witnesses**

6 The parties do not propose to rely on live or deposition testimony of witnesses for purposes
7 of claim construction

8 Dated: November 28, 2011

STEPHEN S. RABINOWITZ
RANDY C. EISENSMITH
FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP

DARALYN J. DURIE
JOSHUA H. LERNER
GENEVIEVE P. ROSLOFF
DURIE TANGRI LLP

/s/ Joshua H. Lerner

14 By: _____
JOSHUA H. LERNER

Attorneys for Plaintiffs
GENENTECH, INC. and
ROCHE PALO ALTO LLC

/s/ Jessica La Londe

18 Dated: November 28, 2011

By: _____

DUANE MORRIS LLP

JESSICA E. LA LONDE
RICHARD T. RUZICH
ROBERT M. GOULD
KERRY B. MCTIGUE
VINCENT L. CAPUANO
LAURA A. VOGEL

Attorneys for Defendant
SANDOZ INC.

25 I, Joshua H. Lerner, am the ECF User whose identification and password are being used to
26 file this document. Pursuant to General Order 45.X.B, I hereby attest that counsel for Defendant
27 Sandoz Inc. has concurred in this filing.

/s/ Joshua H. Lerner